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(Original Signature of Member)

117TH CONGRESS
2D SESSION

H. R. _____

To establish the Food Safety Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, enforcing pesticide residue tolerances, improving the surveillance of foodborne pathogens, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Ms. DELAURO introduced the following bill; which was referred to the Committee on _____

A BILL

To establish the Food Safety Administration to protect the public health by ensuring the safety of food, preventing foodborne illness, maintaining safety reviews and reassessments of food additives, enforcing pesticide residue tolerances, improving the surveillance of foodborne pathogens, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Food Safety Adminis-
3 tration Act of 2022”.

4 **SEC. 2. DEFINITIONS.**

5 In this Act:

6 (1) ADMINISTRATION.—The term “Administra-
7 tion” means the Food Safety Administration estab-
8 lished under section 101(a)(1).

9 (2) ADMINISTRATOR.—The term “Adminis-
10 trator” means the Administrator of Food Safety ap-
11 pointed under section 101(a)(2).

12 (3) FACILITY.—The term “facility” means any
13 factory, warehouse, or establishment that is subject
14 to the requirements of section 415 or 419 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 350d; 350h).

17 **SEC. 3. EFFECTIVE DATE.**

18 This Act, including the amendments made by this
19 Act, shall take effect 180 days after the date of enactment
20 of this Act.

21 **SEC. 4. FUNDING.**

22 (a) TRANSFER OF FUNDS.—The appropriations, allo-
23 cations, and other funds that relate to the authorities,
24 functions and agencies transferred under section 102 shall
25 be transferred to the Administration.

1 (b) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section,
3 such sums as may be necessary for fiscal year 2023 and
4 each fiscal year thereafter.

5 **TITLE I—ESTABLISHMENT OF**
6 **FOOD SAFETY ADMINISTRATION**

7 **SEC. 101. ESTABLISHMENT OF FOOD SAFETY ADMINISTRA-**
8 **TION.**

9 (a) ESTABLISHMENT.—

10 (1) IN GENERAL.—There is established within
11 the Department of Health and Human Services an
12 agency to be known as the “Food Safety Adminis-
13 tration”.

14 (2) HEAD OF ADMINISTRATION.—The Adminis-
15 tration shall be headed by the Administrator of Food
16 Safety, who shall have food safety expertise, and be
17 appointed by the President, by and with the advice
18 and consent of the Senate.

19 (3) EFFECT.—The Federal Food and Drug Ad-
20 ministration shall be renamed “Federal Drug Ad-
21 ministration” and retain responsibility for carrying
22 out its responsibilities related to drugs, cosmetics,
23 devices, biological products, color additives, and to-
24 bacco. The Commissioner of Food and Drugs shall
25 be renamed the “Commissioner of Drugs”, and shall

1 retain the responsibilities of the Commissioner of
2 Food and Drugs, except such responsibilities that re-
3 late to food, which shall be assumed by the Adminis-
4 trator of Food Safety. Each reference in statute to
5 the “Food and Drug Administration” shall be
6 deemed a reference to the “Federal Drug Adminis-
7 tration”, and each reference in statute to the “Com-
8 missioner of Food and Drugs” shall be deemed a
9 reference to the “Commissioner of Drugs”.

10 (b) DUTIES OF THE ADMINISTRATOR.—The Adminis-
11 trator shall—

12 (1) administer and enforce all authorities under
13 chapter IV of the Federal Food, Drug, and Cosmetic
14 Act (21 U.S.C. 341 et seq.);

15 (2) serve as a representative to international
16 food safety bodies and discussions;

17 (3) promulgate and enforce regulations to en-
18 sure the security of the food supply from all forms
19 of contamination, including intentional contamina-
20 tion; and

21 (4) oversee—

22 (A) implementation of Federal food safety;

23 (B) inspection, labeling, enforcement, and
24 research efforts to protect the public health;

1 (C) development of consistent and science-
2 based standards for safe food;

3 (D) safety reviews and reassessments of
4 food additives;

5 (E) establishment and enforcement of tol-
6 erances for poisonous or deleterious substances;

7 (F) monitoring and enforcement of pes-
8 ticide residue tolerances in or on foods;

9 (G) coordination and prioritization of food
10 safety research and education programs with
11 other Federal agencies;

12 (H) prioritization of Federal food safety
13 efforts and deployment of Federal food safety
14 resources to achieve the greatest benefit in re-
15 ducing foodborne illness;

16 (I) coordination of the Federal response to
17 foodborne illness outbreaks with other Federal
18 and State agencies;

19 (J) integration of Federal food safety ac-
20 tivities with State and local agencies; and

21 (K) assignment of tolerances for animal
22 drugs used in food-producing animals.

1 **SEC. 102. TRANSFER OF AUTHORITY, FUNCTIONS AND**
2 **AGENCIES.**

3 (a) TRANSFER OF AUTHORITY.—The Agency shall
4 assume responsibility for carrying out chapter IV of the
5 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341
6 et seq.) and maintain all enforcement authorities with re-
7 spect to food held by the Food and Drug Administration
8 on the date of enactment of this Act.

9 (b) TRANSFER OF FUNCTIONS.—For each Federal
10 agency, office, and center specified in subsection (c), there
11 are transferred to the Administration all functions that
12 the head of the Federal agency exercised on the day before
13 the date of enactment of this Act (including all related
14 functions of any officer or employee of the Federal agency)
15 that relate to administration or enforcement of the food
16 safety law, as determined by the President.

17 (c) TRANSFERRED AGENCIES.—The Federal agencies
18 referred to in subsection (b) are—

19 (1) the resources and facilities of the Center for
20 Food Safety and Applied Nutrition of the Food and
21 Drug Administration that administer chapter IV of
22 the Federal Food, Drug, and Cosmetics Act (21
23 U.S.C. 341 et seq.);

24 (2) the resources and facilities of the Office of
25 Regulatory Affairs of the Food and Drug Adminis-

1 tration that administer and conduct inspections of
2 food and feed facilities and imports;

3 (3) the resources and facilities of the Center for
4 Veterinary Medicine of the Food and Drug Adminis-
5 tration that administer chapter IV of the Federal
6 Food, Drug, and Cosmetics Act (21 U.S.C. 341 et
7 seq.);

8 (4) the Office of Food Policy and Response of
9 the Food and Drug Administration; and

10 (5) such other offices, services, or agencies as
11 the President designates by Executive order to carry
12 out this Act.

13 (d) CONFORMING AMENDMENT.—Subchapter A of
14 chapter VII of the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 371 et seq.) is amended by adding at the end
16 the following:

17 **“SEC. 703. REGULATION OF FOOD.**

18 “Notwithstanding any other provision of this Act, be-
19 ginning on the date that is 180 days after the date of
20 enactment of the Food Safety Administration Act of 2022,
21 any authority under this Act that relates to food shall be
22 under the authority of the Food Safety Administration,
23 and shall be carried out by the Administrator of Food
24 Safety. Any reference in this Act to authorities related to

1 food held by the Secretary shall be deemed to be references
2 to authorities held by the Administrator of Food Safety.”.

3 **SEC. 103. ADDITIONAL DUTIES OF THE ADMINISTRATION.**

4 (a) OFFICERS AND EMPLOYEES.—The Administrator
5 may—

6 (1) appoint officers and employees for the Ad-
7 ministration in accordance with the provisions of
8 title 5, United States Code, relating to appointment
9 in the competitive service; and

10 (2) fix the compensation of those officers and
11 employees in accordance with chapter 51 and with
12 subchapter III of chapter 53 of that title, relating to
13 classification and General Schedule pay rates.

14 (b) EXPERTS AND CONSULTANTS.—The Administra-
15 tion may—

16 (1) procure the services of temporary or inter-
17 mittent experts and consultants as authorized by
18 section 3109 of title 5, United States Code; and

19 (2) pay in connection with those services the
20 travel expenses of the experts and consultants, in-
21 cluding transportation and per diem in lieu of sub-
22 sistence while away from the homes or regular
23 places of business of the individuals, as authorized
24 by section 5703 of that title.

1 (c) BUREAUS, OFFICES, AND DIVISIONS.—The Ad-
2 ministrator may establish within the Administration such
3 bureaus, offices, and divisions as the Administrator deter-
4 mines are necessary to perform the duties of the Adminis-
5 trator.

6 (d) ADVISORY COMMITTEES.—

7 (1) IN GENERAL.—The Administrator shall es-
8 tablish advisory committees that consist of rep-
9 resentative of scientific expert bodies, academics, in-
10 dustry specialists, and consumers.

11 (2) DUTIES.—The duties of an advisory com-
12 mittee established under paragraph (1) may include
13 developing recommendations with respect to the de-
14 velopment of regulatory science and processes, re-
15 search, communications, performance standards, and
16 inspection.

17 **TITLE II—ADMINISTRATION OF** 18 **FOOD SAFETY PROGRAM**

19 **SEC. 201. ESTABLISHMENT OF INSPECTION PROGRAM.**

20 (a) IN GENERAL.—The Administrator shall establish
21 an inspection program, which shall include inspections of
22 food facilities subject to subsection (b) and in accordance
23 with section 202.

24 (b) FACILITY CATEGORIES.—Not later than 6
25 months after the date of enactment of this Act, the Ad-

1 ministrator shall issue formal guidance defining the cri-
2 teria by which food facilities will be divided into “high-
3 risk,” “intermediate risk,” and “low-risk” facilities.

4 (c) INSPECTION FREQUENCIES.—Frequency of in-
5 spections of food facilities under this Act shall be based
6 on the categories defined pursuant to subsection (b) and
7 in accordance with section 202.

8 **SEC. 202. INSPECTIONS OF FOOD FACILITIES.**

9 (a) FREQUENCY OF INSPECTIONS.—

10 (1) HIGH-RISK FACILITIES.—The Administrator
11 shall inspect high-risk facilities not less than once
12 per a year.

13 (2) “INTERMEDIATE-RISK FACILITIES .—The
14 Administrator shall inspect intermediate-risk facili-
15 ties not less than once every 2 years.

16 (3) “LOW-RISK FACILITIES.—The Administrator
17 shall inspect low risk facilities, which shall include
18 warehouses or similar facilities that engage in pack-
19 aging or distribution, and pose very minimal public
20 health risk, not less than once every 3 years.

21 (b) INFANT FORMULA MANUFACTURING FACILI-
22 TIES.—The Administrator shall inspect the facilities of
23 each manufacturer of infant formula not less than every
24 6 months.

1 (c) FEDERAL AND STATE COOPERATION.—The Ad-
2 ministrator shall contract with State officials to carry out
3 half of the safety inspections required under this section.

4 **SEC. 203. COMPLIANCE CHECKS.**

5 Not later than 30 days after issuing a form that is
6 equivalent to an FDA Form 483 to a facility, pursuant
7 to an inspection under section 704 of Federal Food, Drug,
8 and Cosmetic Act (21 U.S.C. 374), the Administrator
9 shall conduct a follow-up compliance check with the facil-
10 ity.

11 **SEC. 204. TRACEABILITY RULE.**

12 Not later than November 7, 2022, the Administrator
13 shall promulgate a final rule that is based on the proposed
14 rule issued by the Food and Drug Administration titled,
15 “Requirements for Additional Traceability Records for
16 Certain Foods” (85 Fed. Reg. 59984 (Sept. 23, 2021)).

17 **SEC. 205. NOTICE OF CIRCUMSTANCES THAT COULD LEAD**
18 **TO A SHORTAGE.**

19 Chapter IV of the Federal Food, Drug, and Cosmetic
20 Act (21 U.S.C. 341 et seq.) is amended by adding at the
21 end the following:

22 **“SEC. 424. NOTICE OF CIRCUMSTANCES THAT COULD LEAD**
23 **TO A SHORTAGE.**

24 “(a) NOTICE REQUIREMENT.—Not later than 5 busi-
25 ness days after a manufacturer of infant formula or essen-

1 tial medical food becomes aware of circumstances that
2 could lead to a shortage of infant formula or essential
3 medical food in the United States, such manufacturer
4 shall give written notice of such circumstances to the Ad-
5 ministrator.

6 “(b) FINES.—If the Administrator finds that a man-
7 ufacturer of infant formula or essential medical food is
8 in violation of the requirement of this section to give writ-
9 ten notice, such violation shall be treated as an infraction
10 for purposes of imposing a fine in accordance with title
11 18, United States Code.

12 “(c) DEFINITIONS.—In this section:

13 “(1) The term ‘Administrator’ means the Ad-
14 ministrator of Food Safety.

15 “(2) The term ‘essential medical food’ means a
16 food that—

17 “(A) is formulated to be consumed or ad-
18 ministered enterally under the supervision of a
19 physician;

20 “(B) is intended for the specific dietary
21 management of a disease or condition for which
22 distinctive nutritional requirements, based on
23 recognized scientific principles, are established
24 by medical evaluation; and

1 “(C) is identified by the Administrator as
2 being essential for any urgent medical condi-
3 tion.”.